

**REMARKS**

Claims 22, 25-27, 29-48 are pending in the application. This Response is being filed with a Request for Continued Examination and a petition for a three month extension of time and appropriate fees.

35 U.S.C. §103(a), quoted in the rejection, requires an evaluation of whether “the differences between the subject matter sought to be patented and the prior art are such that the **subject matter as a whole** would be obvious **at the time the invention was made to a person having ordinary skill in the art** to which said subject matter pertains...” (*emphasis added*). The subject matter as a whole reduces, then, to the distinguishing features clearly incorporated into the claims. *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459, 473 (1966). The Supreme Court has recently re-affirmed the *Graham* analysis. “[T]he scope and content of the prior art are ... determined; differences between the prior art and the claims at issue are ... ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.” *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1388 (U.S. 2007).

**Claim Rejections under 35 U.S.C. §103(a)**

1). Claims 22, 25-27, 29-48 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Sallis et al. (U.S. 7,405,222, effective filing date of January 25, 2002) in view of Yeager et al. (WO 01/51053, publication date 19 July 2001). The Applicant respectfully submits that the rejection under 35 U.S.C. §103(a) of Claims 22, 25-27, 29-48 is unwarranted and requests that the rejection be withdrawn.

The Applicant respectfully traverses the Examiner's characterization of the teaching of the Sallis et al. reference. As previously stated in detail, the relevant teachings of the Sallis et al. reference are internally contradictory. A careful review of the file history of the Sallis et al. reference and the priority document USSN 60/351,634 provided no further evidence to resolve the contradictory descriptions of composition F6 in the Sallis et al. reference. The reference must be considered for what it teaches as a whole, and not cherry-picked to support the argument, while ignoring the contradictions. Therefore, the Applicant submits that there is no unambiguous teaching of the Sallis et al. reference regarding the diagnosis or treatment of premature ejaculation using compositions containing prostaglandin E<sub>1</sub>.

Given the ambiguity of the teaching of the Sallis et al. reference on the diagnosis or treatment of premature ejaculation using compositions containing prostaglandin E1, the Applicant respectfully submits there is no unequivocal basis in fact for assertions such as "Sallis et al. teach a method of treating premature ejaculation comprising administering a vasodilator such as Prostaglandin E1" (Office Action, page 6, lines 10-11), or "The [Sallis et al.] reference teaches administration of prostaglandin in a method of treatment of premature ejaculation" (Office Action, page 7, lines 19-20), or "One of ordinary skill in the art would have been motivated to administer the composition of Yeager in a method of treatment of premature ejaculation in expectation of success because Sallis teach administration of prostaglandin E1 in a method of treating premature ejaculation . . ." (Office Action, page 7, last line, to page 8, 19-20).

Even if there were an unambiguous teaching in Sallis et al. regarding the diagnosis or treatment of premature ejaculation using compositions containing prostaglandin E1, one of ordinary skill in the art would not be led to combine the teachings of the Sallis et al. reference and the teachings of the Yeager et al. WO 01/51053 reference to arrive at the presently claimed invention because the Sallis et al. reference teaches a different mode of administration than either the Yeager et al. WO 01/51053 reference or the presently claimed invention. The Yeager et al. WO 01/51053 reference and the present invention teach the non-traumatic application of the semisolid composition to the meatus of the penis into the naturally occurring space of the *fossa navicularis* of the penis. The Sallis et al. reference teaches the more invasive hypodermic injection of compositions into the corpora cavernosa of the penis.

The Examiner argues that absent some demonstration of unexpected results from the claimed parameters, this optimization of route of administration would have been obvious at the time of applicant's invention. However, unexpected, statistically significant, results have been obtained in the practice of the presently claimed invention as disclosed in the present application at pages 35-53, and in particular in Tables 18 and 19.

In summary, the Applicant respectfully submits that the rejection under 35 U.S.C. §103(a) of Claims 22, 25-27, 29-48 over the combination of the Sallis et al. reference and the Yeager et al. WO 01/51053 reference is unwarranted and requests that the rejection be withdrawn.

2. Claims 22, 25-27, and 29-48 have been rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Sallis et al. (U.S. 7,405,222, effective filing date of January 25, 2002) in view of Yeager et al. (US 2002/0045665, publication date April 18, 2002). The Applicant respectfully submits that the rejection under 35 U.S.C. §103(a) of Claims 22, 25-27, 29-48 is unwarranted and requests that the rejection be withdrawn.

The Sallis et al. reference is discussed in detail above. The Yeager et al US2002/0045665 reference is stated on its face page to be a continuation-in-part of application No. 09/480,738, filed on Jan. 10, 2000, now Pat. No. 6,323,241, and a continuation-in-part of application No. PCT/US01/00852, filed on Jan. 10, 2001, which was published as WO 01/51053 on July 19, 2001. The teachings and suggestions of the Yeager et al. US2002/0045665 reference are thus substantially similar to the teachings and suggestions of the Yeager et al. WO 01/51053 reference discussed above.

For the reasons discussed above, the Applicant submits that there is **no unambiguous teaching** of the Sallis et al. reference regarding the diagnosis or treatment of premature ejaculation using compositions containing prostaglandin E<sub>1</sub>. The Applicant submits that one of ordinary skill in the art would recognize the internal contradiction in the teachings of the Sallis et al. reference regarding the diagnosis or treatment of premature ejaculation using compositions containing prostaglandin E<sub>1</sub>, and would not rely on the teachings of the Sallis et al. reference in the area of diagnosis or treatment of premature ejaculation, either alone, or in combination with the Yeager et al. US2002/0045665 reference.

The Applicant respectfully traverses the Examiner's position that is not supported by any facts of record:

It would have been obvious to one of ordinary skill in the art at the time of the invention that composition comprising the same components as claimed when applied to the same set of population will have the same properties and function and hence the ejaculation latency time will be no less than two minutes or will be greater than two minutes and will be prolonged by at least two minutes as claimed in claims 44-46. Office Action, page 9, lines 9-14.

To the contrary, there is ample evidence in the record that the population of patients having premature ejaculation is heterogeneous, that premature ejaculation may have several etiologies, and a patient with premature ejaculation may also suffer from various other sexual dysfunctions. *See* the present application as filed, page 4, lines 6-28; Chia, S.J., Management of premature ejaculation - a comparison of treatment outcome in patients with and without erectile dysfunction, Int. Journal of Andrology, 2002, 25:301-305, of record, McMahon, C.G., et al., Disorders of Orgasm and Ejaculation in Men, J Sexual Medicine, 2004 Jul;1(1):58-65, of record, and Lue, T.F., et al., Summary of the recommendations on sexual dysfunctions in men, J Sexual Medicine. 2004 Jul;1 (1):6-23, of record. The McMahon et al. and Lue et al. references are summaries of recommendations presented at the 2<sup>nd</sup> International Consultation on Sexual Medicine in Paris, France, June 28-July 1, 2003.

For the reasons discussed in detail above, the Sallis et al. reference and the Yeager et al. US2002/0045665 reference, alone or in combination, neither teach nor suggest the presently claimed

invention. The Applicant respectfully submits that the rejection of Claims 22, 25-27, 29-48 under 35 U.S.C. §103(a) based on the Sallis et al. reference and the Yeager et al. US2002/0045665 reference is unwarranted and requests that the rejection be withdrawn.

3. Claims 22, 25-27, 29-48 have been rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Doherty et al. (U.S. 6,037,346) in view of Yeager et al. (WO 01/51053, publication date 19 July 2001). The Applicant respectfully submits that the rejection under 35 U.S.C. §103(a) of Claims 22, 25-27, 29-48 is unwarranted and requests that the rejection be withdrawn. The Yeager et al. WO 01/51053 reference has been discussed above.

The Doherty, et al. reference, U.S. Patent No. 6,037,346, for “Local Administration Of Phosphodiesterase Inhibitors For The Treatment Of Erectile Dysfunction” relates to a method for treating erectile dysfunction in a mammalian male individual involving the local administration of a phosphodiesterase inhibitor or a pharmaceutically acceptable salt, ester, amide or derivative thereof within the context of an effective dosing regimen, where a preferred mode of administration is transurethral. Doherty et al. Abstract. The Examiner notes that the Doherty et al. reference states that “the term ‘erectile dysfunction’ is intended to include any and all types of erectile dysfunction, including: vasculogenic, neurogenic, endocrinologic and psychogenic impotence, Peyronie's syndrome; priapism, premature ejaculation (PE) and any other condition, disease or disorder, regardless of cause or origin, which interferes with at least one of the three phases of human sexual response, i.e., desire, excitement and orgasm (col. 5, lines 42-54).” Office Action, page 10, lines 1-6 (*emphasis added*). The Examiner then states that “An applicant is entitled to be his or her own lexicographer (see MPEP 2111.01).”

The principle that an applicant is entitled to be his or her own lexicographer is a rule of claim construction that is employed as an exception to the general practice that terms in a claim are given the their ordinary and customary meaning. For reasons of record that have previously been discussed in detail, the appeal to that principle in the present context is an admission that the Doherty et al. definition of ‘erectile dysfunction’ is contrary to the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention. One of ordinary skill in the art would apply the art-recognized definition of “erectile dysfunction” which is different from the art-recognized definition of “premature ejaculation.”

For the reasons discussed in detail above, the Doherty et al. reference and the Yeager et al. WO 01/51053 reference, alone or in combination, neither teach nor suggest the presently claimed invention. The Applicant respectfully submits that the rejection of Claims 22, 25-27, 29-48 under 35 U.S.C. §103(a)

based on the Doherty et al. reference and the Yeager et al. WO 01/51053 reference is unwarranted and requests that the rejection be withdrawn

4. Claims 22, 25-27, 29-48 have been rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Doherty et al. (U.S. 6,037,346) in view of Yeager et al. (US 2002/0045665, publication date April 18, 2002). The Applicant respectfully submits that the rejection under 35 U.S.C. §103(a) of Claims 22, 25-27, 29-48 is unwarranted and requests that the rejection be withdrawn. Both the Doherty et al. reference and the Yeager et al. US 2002/0045665 reference have been discussed in detail above. The Applicant submits that the Doherty et al. reference and the Yeager et al. US 2002/0045665 reference, alone or in combination, neither teach nor suggest the presently claimed invention, and the rejection of Claims 22, 25-27, 29-48 under 35 U.S.C. §103(a) based on the Doherty et al. reference and the Yeager et al. US 2002/0045665 reference is unwarranted, and should be withdrawn.

### Conclusion

In light of the amendments and arguments presented herein, the Applicant respectfully submits that all pending claims are in condition for allowance and requests a timely Notice of Allowance to follow in this case. This paper is being filed timely as it is being filed with a Request for Continued Examination and a petition for a three month extension of time and appropriate fees. In the event any additional extensions of time, fees and/or credits are necessary, please consider this a conditional petition therefor. The undersigned hereby authorizes the requisite fees to be charged and/or credited accordingly to Deposit Account No. 50-1582.

If at any time a telephone discussion would assist the Examiner and/or advance prosecution, please contact the undersigned at 508-860-1472 (direct line).

Respectfully submitted,

April 14, 2010 MIRICK, O'CONNELL, DEMALLIE & LOUGEE, LLP

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